

AUG 16 2004

K04/650

# **510(k) Summary**

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**Submitted on behalf of:**

**Company Name:** InnovX Medical, Inc.  
**Address:** 16631 78<sup>th</sup> Avenue North  
Maple Grove, MN 55311  
**Telephone:** 763-442-1384

**by:** Elaine Duncan, M.S.M.E., RAC  
President, Paladin Medical, Inc.  
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Stillwater, MN 55082  
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**CONTACT PERSON:** Elaine Duncan  
**DATE PREPARED:** June 9, 2004

**TRADE NAME:** Micro Prime Delivery Lines  
**COMMON NAME:** Aarterial and cardioplegia delivery tubing

**SUBSTANTIALLY EQUIVALENT TO:**

Micro Prime is substantially equivalent to conventional cardiopulmonary blood and cardioplegia lines with the difference of reduced priming volume. Silicone materials used to produce this unique design are biocompatible. Silicone cardiopulmonary bypass components have been used safely for more than two decades (K843444.) Predicate product, such as the Medtronic One Piece Pediatric Cannula are focused to the pediatric patient's special needs (K024069) Standard tubing sets (arterial and cardioplegia) from PVC are well recognized in the predicate device literature (K803277 predicate use of Tygon PVC tubing, and K964205, Better-Tubing <sup>TM</sup>)

**DESCRIPTION of the DEVICE:** Micro Prime Delivery Lines minimize the blood prime volume in the extracorporeal circuit. For pediatric cardiopulmonary bypass, where excessive priming volume can increase surgical risk, Micro Prime delivery lines offer a distinct advantage. Micro Prime Delivery Lines consist of a dual lumen extrusion: a round "blood" lumen used to convey blood to/from the patient, and a crescent shaped "occlusion" lumen which surrounds the blood lumen, and is used to purge excess prime volume from the blood lumen.

In use, both lumens are initially primed with saline. Once the tubing has been primed, the occlusion lumen is pressurized with additional saline, collapsing the blood lumen and purging excess priming fluid from the blood lumen. Releasing the pressure from the occlusion lumen causes the blood lumen to re-open to its normal shape. In this manner, Micro Prime Delivery Lines require negligible blood volume to prime as compared to conventional delivery lines.

**INDICATIONS FOR USE:**

Micro Prime Delivery Lines are indicated for use to convey arterial blood and cardioplegia with minimal prime volume in the extracorporeal circuit.

**SUMMARY of TESTING:**

InnovX Medical, Inc. conducted functional testing for Micro Prime delivery line samples, which had been ethylene oxide sterilized twice, aged for the equivalent of one year, and ship tested at cold and at warm temperatures. Units passed functional requirements.

Biocompatibility testing and reference to Device Master File for silicone rubber extrusion demonstrate suitability of the materials.

The potential for blood trauma was assessed over a 6-hour period using bovine blood in five 3/16" ID Micro Prime delivery tubes and five 3/16" ID conventional extracorporeal delivery tubes, flowing through a simulated extracorporeal circuit. Blood trauma was assessed by measuring plasma hemoglobin, white blood cell count, and platelet count at half hour intervals over the duration of the test. Statistical analysis of the data using hypothesis test of means indicates that blood trauma associated with Micro Prime Delivery Tubes is comparable to blood trauma for conventional delivery tubes.

Pressure drop data was simultaneously monitored across the ten samples in the blood trauma evaluation to assess whether Micro Prime Delivery Tubes had a negative impact on pressure in the extracorporeal circuit. Analysis of this data indicates that pressure drop in Micro Prime Delivery Tubes is nominally lower than conventional delivery tubes.

Comparison of sterile/aged, non-sterile-non aged product revealed there is no statistically significant difference between groups. Package Integrity Ship Testing for one year aging showed no changes to the specimens and that the package held integrity under the conditions tested. Design Verification was conducted to assure product met criteria. Positive pressure experiments (arterial and cardioplegia) met all acceptance criteria and are qualified for 2c ETO and one-year shelf life. Due to the results from venous drainage experiments, the Micro Prime Delivery Line is contraindicated for venous drainage.

Testing confirmed that the design did not introduce any new safety concerns and performed equivalent to or better than conventional PVC cardiopulmonary bypass lines.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**AUG 16 2004**

InnovX Medical, Inc.  
c/o Elaine Duncan  
16631 78<sup>th</sup> Avenue North  
Maple Grove, MN 55311

Re: K041650  
Micro Prime Delivery Lines  
Regulation Number: 870.4210  
Regulation Name: Vascular Catheter, Cannula, or Tubing Cardiopulmonary Bypass  
Regulatory Class: Class II (two)  
Product Code: 74 DWF  
Dated: June 15, 2004  
Received: June 17, 2004

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

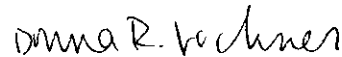
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known). K041650

Device Name: Micro Prime Delivery Lines

Indications For Use:

Micro Prime Delivery Lines are indicated for use to convey arterial blood and cardioplegia with minimal prime volume in the extracorporeal circuit.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Vachner  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K041650

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